

ORWH FY 02 SUPPORTED SPECIAL PROJECTS

TITLE: Sister to Sister Foundation: Everyone Has a Heart Health Fair NHLBI
AWARD: \$20,000
CONTACT: Greg Morosco, Ph.D.

The **Sister to Sister – Everyone Has A Heart Foundation** was founded to increase awareness about heart disease as the number one killer of women and to encourage healthy lifestyles. It is the only national organization whose focus is on screening women for heart disease. Because of the lack of awareness among women about the seriousness of heart disease and the belief that women can modify, control, or treat their risk factors for this disease, the Foundation's mission is:

- To provide women with opportunities to be screened for early detection and treatment of heart disease, and
- To educate women about prevention measures, including a healthy diet, regular exercise, stress management, and smoking cessation to reduce heart disease risk factors.

The Foundation sponsored a second health fair in Washington, DC on February 22, 2002 and will duplicate the campaign in other cities in 2003 and beyond. ORWH provided \$20,000 (\$8,000 screening kits and \$12,000 data analysis) to expand screenings during the February 2002 *Woman's Heart Day* campaign. This activity supports and reinforces the public outreach efforts and activities of the National Institutes of Health and in particular those of the National Heart, Lung and Blood Institute and the ORWH.

TITLE: Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCORs)
AWARD: ORWH - \$8.7 M
CONTACT: Dr. Charisee Lamar NIAMS

ORWH funded eleven new Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCORs.). Funding for the Centers will total approximately 11 million per year for 5 years with co-funding by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Child Health and Human Development (NICHD), The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), The National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and the National Institute of Environmental Health Sciences (NIEHS) and the Food and Drug Administration (FDA.) These centers will provide new opportunities for interdisciplinary approaches to advancing studies on how sex and gender factors affect women's health.

Each SCOR will promote interdisciplinary collaborations and develop a research agenda bridging basic and clinical research on sex/gender factors underlying a priority health issue. The SCOR program will complement other Federally supported programs addressing women's health issues. Such programs include the Building Interdisciplinary Research Careers in Women's Health

(BIRCWH), the Women's Reproductive Health Research Career Development Centers (WRHR), and numerous NIH RFA's and PAs.

This is the first time the ORWH has taken the lead in developing and funding a new research initiative relating to women's health. The multidisciplinary nature of the centers will provide innovative approaches to advancing research on the role of sex and gender related health effects. The research scope of the SCOR's stems from three sources: the Institute of Medicine (IOM) report, "Exploring the Biological Contributions to Health Does Sex Matter?", "An Agenda for Research on Women's Health for the 21st Century", and from recommendations from the National Institutes of Health (NIH) Institutes and Centers. The multidisciplinary nature of these centers will provide opportunities for innovative approaches to research on the role of sex- and gender-related health effects.

Thirty-six applications containing 184 projects were received in response to the SCOR RFA: OD-02-002 but one was withdrawn by the applicant prior to review. Applications were reviewed in two phases due to the number and diversity of the projects. Phase one reviewers provided critiques and scores based on scientific merit of the individual projects.

There was no review meeting for Phase one. Scores and critiques were made available to Phase two reviewers through the Internet-Assisted Review System. Phase two reviewers read the critiques and scores of each application prior to attending review session. The Phase two committee consisted of investigators experienced in running Centers funded by NIH Institutes. Overall scores were determined by the combination of the two-phase review.

The SCORs were selected on the basis of having at least three highly meritorious interdisciplinary research projects that explore an important issue related to sex/gender health differences related by a common theme. Individual projects must be related by a common theme, which encompasses clinical and basic research. An administrative unit at each institution oversees coordination of the individual projects. Research priority areas, including mental health, reproductive health, pain disorders, and urinary tract health, will be addressed by grantees of this new ORWH initiative.

The primary institute program director will review the annual progress reports submitted by the SCOR's, and will provide a yearly report on the scientific progress of the grantee. The ORWH SCOR Coordinator will oversee the applications to coordinate policy issues for the overall program. The SCOR Coordinator will make site visits, arrange annual meetings of the investigators, and write reports on the program for the Director of the ORWH.

Research priority areas including mental health, reproductive health, pain disorders, and urinary tract health will be addressed by the new Centers. The following section outlines SCOR themes, center directors, individual projects, and affiliations.

Emory University: Pharmacology of anti-epileptic and psychotropic medications during pregnancy and lactation, Zachary Stowe, M.D.

Medical University of South Carolina: Role of sex and gender differences in substance abuse relapse, Kathleen Brady, M. D., Ph.D.

Northwestern University: Genes, androgens and intrauterine environment in polycystic ovarian syndrome (PCOS), Andrea Dunaif, M.D.

University of California, Los Angeles: Sex and gender factors in the pathophysiology of irritable bowel syndrome (IBS) and interstitial cystitis (IC), Emeran Mayer, M.D.

University of California, San Francisco: Mechanisms underlying female urinary incontinence, Jeanette Brown, M.D.

University of Maryland: Sex differences in pain sensitivity, Joel Greenspan, Ph.D.

University of Michigan, Ann Arbor: Birth, muscle injury and pelvic floor dysfunction, John DeLancey, M.D.

University of Pittsburgh: Genetic and environmental origins of adverse pregnancy outcomes, Gerald Schatten, Ph.D.

University of Washington: Mechanisms by which drug transporters alter maternal and fetal drug exposure during pregnancy, Jashvant Unadkat, Ph.D.

Washington University: Molecular and epidemiologic basis of acute and recurrent urinary tract infections (UTI's) in women, Scott Hultgren, Ph.D.

Yale University: Sex, stress and cocaine addiction, Rajita Sinha, Ph.D.

Institution: Emory University
Center Director: Zachary Stowe, M.D.
Grant Number: P50MH068036

SCOR Theme: Pharmacology of anti-epileptic and psychotropic medications during pregnancy and lactation

Principal Investigator	Project Title
Zachary Stowe, M.D.	Administrative Core
Page Pennell, M.D.	Epilepsy and Child Birth: Pharmacokinetics/Pharmacodynamic Modeling of Antiepileptic Drugs
Zachary Stowe, M.D.	Mood and Anxiety Disorders in Pregnancy and Lactation: Pharmacokinetics/Pharmacodynamic Modeling of Psychotropic Medications
Michael Owens, Ph.D.	Antiepileptic Drugs and Psychotropics in Pregnancy:

	Rodent Model
Lindsay Devane, Pharm.D.	Pharmacokinetics/Pharmacodynamic/Pharmacogenetic Modeling Core
James Ritchie, Ph.D.	Assay Core

Institution: Medical University of South Carolina
Center Director: Kathleen Brady, M.D., Ph.D.
Grant Number: P50DA016511

SCOR Theme: Role of sex and gender differences in substance abuse relapse

Principal Investigator	Project Title
Kathleen Brady, M.D., Ph.D.	Administrative Core
Ronald See, Ph.D.	Sex Differences in an Animal Model of Relapse
Kathleen Brady, M.D., Ph.D.	Gender Difference in Response to Cues in Cocaine Dependence
Himanshu Upadhyaya, M.D.	Gender, Menstrual Cycle and Smoking Cue Reactivity
Lawrence Middaugh, Ph.D.	Gender Influence on Preclinical Alcohol Pharmacology

Institution: Northwestern University
Center Director: Andrea Dunaif, M.D.
Grant Number: P50HD044405

SCOR Theme: Genes, androgens and intrauterine environment in polycystic ovarian syndrome

Principal Investigator	Project Title
Andrea Dunaif, M.D.	Administrative Core
Andrea Dunaif, M.D.	Gene, Intrauterine Environment and Polycystic Ovarian Syndrome
Margrit Urbanek, Ph.D.	Identification of Chromosome 19 Polycystic Ovarian Syndrome Susceptibility Gene
David Abbott, Ph.D.	Fetal Androgen Induces Ovarian, LH and B-Cell Defects
Jon Levine, Ph.D.	Neuroendocrine Actions of Androgens in Females

Institution: University of Maryland
Center Director: Joel Greenspan, Ph.D.
Grant Number: P50AR049555

SCOR Theme: Sex differences in pain sensitivity

Principal Investigator	Project Title
Joel Greenspan, Ph.D.	Administrative Core
Michael Gold, Ph.D.	Ionic Mechanisms of Temporomandibular Joint Pain
Joel Greenspan, Ph.D.	CNS Mechanisms for Gender Differences in Pain, and

	Their Relevance to Temporomandibular Disorder Pain
Anne Murphy, Ph.D.	Sex Differences in Visceral Pain: Influence of Gonadal Steroids

Institution: University of California, Los Angeles
Center Director: Emeran Mayer, M.D.
Grant Number: P50DK064539

SCOR Theme: Sex and gender factors in the pathophysiology of irritable bowel syndrome and interstitial cystitis

Principal Investigator	Project Title
Emeran Mayer, M.D	Administrative Core
Yvette Tache, Ph.D.	Sex Differences in the Colonic Responses to Stress: Role of Corticotropin-Releasing Factor Pathways
Lin Chang, M.D.	Sex Differences in Neuroendocrine and Immunologic Responses in Irritable Bowel Syndrome
Emeran Mayer, M.D.	Sex Differences in Central Stress Circuit Responsiveness in Irritable Bowel Syndrome and Interstitial Cystitis Patients
Tony Buffington, D.V.M., Ph.D.	Sex Differences in Corticotropin-Releasing Factor, Noradrenergic Function and Oxytocin in Cats with Interstitial Cystitis
Gordon Ohning, M.D., Ph.D.	Neuroendocrine Measures Core

Institution: University of California, San Francisco
Center Director: Jeanette Brown, M.D.
Grant Number: P50DK064538

SCOR Theme: Mechanisms underlying female urinary incontinence

Principal Investigator	Project Title
Jeanette Brown, M.D.	Administrative Core
Jeanette Brown, M.D.	Diabetes: Lower Urinary Tract Dysfunction and Infections
David Thom, M.D., Ph.D.	Urinary Incontinence: Reproductive/Hormonal Risk Factors
Tom Lue, M.D.	Urinary Incontinence: Molecular Mechanism and Matrix-Based Therapy
Eric Vittinghoff, Ph.D.	Biostatistic Core

Institution: University of Michigan, Ann Arbor
Center Director: John DeLancey, M.D.
Grant Number: P50HD044406

SCOR Theme: Birth, muscle injury and pelvic floor dysfunction

Principal Investigator	Project Title
John DeLancey, M.D.	Administrative, Human Subjects, and Biostatistics Core
James Ashton-Miller, Ph.D.	Pelvic Floor Biomechanics and Birth Related Injury
Janis Miller, R.N., Ph.D.	Selection Criteria for Pelvic Muscle Therapy in Stress Urinary Incontinence
John DeLancey, M.D.	Which Pelvic Floor Defects Cause Stress Incontinence?
James Ashton-Miller, Ph.D.	Measurement and Imaging Core

Institution: University of Pittsburgh

Center Director: Gerald Schatten, Ph.D.
Grant Number: P50ES012359

SCOR Theme: Genetic and environmental origins of adverse pregnancy outcomes

Principal Investigator	Project Title
Gerald Schatten, Ph.D.	Administrative Core
Julie DeLoia, Ph.D.	Maternal and Fetal Consequences of Tobacco Smoke Exposure
Gerald Schatten, Ph.D.	Epigenetic, Genetic and Environmental Regulation of Pregnancy in Primates
J. Richard Chaillet, M.D., Ph.D.	Pregnancy Loss: Genomic Imprinting of Skewed X-Inactivation
Eric Ahrens, Ph.D.	Imaging Core
Laura Hewitson, Ph.D.	Pregnancy Core

Institution: University of Washington
Center Director: Jashvant Unadkat, Ph.D.
Grant Number: P50HD044404

SCOR Theme: Mechanisms by which drug transporters alter maternal and fetal drug exposure during pregnancy

Principal Investigator	Project Title
Jashvant Unadkat, Ph.D.	Administrative Core
Jashvant Unadkat, Ph.D.	Changes in Hepatic and Intestinal P-glycoprotein and CYP3A Activity During Pregnancy
Qingcheng Mao, Ph.D.	The breast cancer resistance protein (BCRP) in pregnancy: activity, expression and regulation
Vadivel Ganapathy, Ph.D.	Role of OCT3 in Drug Pharmacokinetics During Pregnancy

Institution: Washington University
Center Director: Scott Hultgren, Ph.D.
Grant Number: P50DK064540

SCOR Theme: Molecular and epidemiologic basis of acute and recurrent urinary tract infections in women

Principal Investigator	Project Title
Scott Hultgren, Ph.D.	Administrative Core
Scott Hultgren, Ph.D.	Host-Pathogen Interactions in Acute and Chronic Urinary Tract Infections
Thomas Hooton, M.D.	Microbial Reservoirs and Urinary Tract Infections in Women
Jeffery Gordon, M.D.	Functional Genomic Studies of Urinary Tract Infections

Institution: Yale University
Center Director: Rajita Sinha, Ph.D.
Grant Number: P50DA016556

SCOR Theme: Sex, stress and cocaine addiction

Principal Investigator	Project Title
Rajita Sinha, Ph.D.	Scientific and Administrative Core
Jane Taylor, Ph.D., Marina Picciotto, Ph.D.	Molecular Basis of Sex Differences in Cocaine Addiction
Therese Kosten, Ph.D.	Early Life Stress and Vulnerability to Cocaine Addiction
Rajita Sinha, Ph.D.	Sex Differences in Stress Related Cocaine Relapse
Thomas Kosten, M.D.	Functional Magnetic Resonance Imaging of Gender and Stress Response in Cocaine Dependence

TITLE: Governors' Spouses Initiative to Curb Underage Drinking **NIAAA**
AWARD: \$100,000
CONTACT: Suzanne Medgyesi-Mitschang, Ph.D.

The Office of Research on Women's Health (ORWH) provided \$100,000 to the National Institute on Alcohol Abuse & Alcoholism (NIAAA) to support the "Governors' Spouses Initiative to Curb Underage Drinking." The Leadership to Keep Children Alcohol Free was

established in 1999 by the NIAAA and the Robert Wood Johnson Foundation (RWJF) in response to the need for leadership in the prevention of alcohol consumption by children aged 9 to 15. Based on the best alcohol research and led by 33 Governors' spouses, this initiative has also been joined by five additional Federal funding partners including the ORWH, the National Center on Minority Health and Health Disparities, the Office of Juvenile Justice and Delinquency Prevention, the Substance Abuse and Mental Health Services Administration, and the National Highway Traffic Safety Administration as well as several national organizations with a shared interest in children's health. The goals of this unique collaboration of Governors' spouses, Federal partners, and national organizations are

1. To raise public awareness about the serious issue of alcohol use by children and
2. To mobilize prevention efforts across the country.

Overall, the initiative has made great strides on a number of fronts. Professionals in the field report that the initiative has re-energized the field of underage drinking prevention across the country. It is also fostering new collaborations among researchers and practitioners. Its message is also being heeded as State legislatures create study groups (Georgia and North Carolina) and to propose legislation related to curtailing alcohol abuse (e.g. Oregon, Ohio, Alaska, Hawaii).

The following are highlights of the initiative's accomplishments to date.

- Number of participating Governors spouses has increased to 33 current spouses and 3 emeritus spouses (Michele Ridge, Sue Ann Thompson, Theresa Racicot). Further recruitment continues with the hope of engaging all 50 States in the initiative, including Puerto Rico.
- Current and former Governors spouses are actively engaged in educating the public, policy makers and youth in their States and nationally through speaking engagements, Op Ed pieces, production of PSA's and videos, poster contests, policy briefings for State legislators and other public officials, alcohol education/prevention conferences, involving youth in prevention efforts, and facilitating collaboration across State and local agencies.
- The membership of the Executive Working Group increased to 28 national organizations, including several national organizations targeting the concerns of diverse cultural and ethnic groups.
- Three publications in English and Spanish were developed and distributed nationally: (1) *Keep Kids Alcohol Free: Strategies for Action (Mantengamos a los niños libres de alcohol: Estrategias para entrar en acción)*, (2) *How Does Alcohol Affect the World of a Child? (¿De qué Manera Afecta el Alcohol el Mundo de un Niño?)*, and (3) *Make a difference: Talk to your Child about Alcohol (Haga La Diferencia: Hable con sus Hijos Sobre el Uso del Alcohol)*.
- A first series of 10 and second series of 7 one-page summaries of studies with relevance to early alcohol use were developed, entitled "Science, Kids, and Alcohol: Research Briefs." Topics covered include the effect of alcohol dependence on brain activity, youth

drinking patterns by sex and race/ethnicity, and proven environmental strategies for reducing underage drinking.

- More than 400,000 publication have been ordered and distributed, with 76,605 documents to 47 States and 8 foreign countries in the last quarter alone (January – March 2002).
- In October 2001 the *Leadership's* new web site was launched and within the first quarter the site had over 11,000 visitors. (www.leadership@alcoholfreechildren.org)
- The Second National Conference – *The Solution is Within Our Reach: Working Together to Keep Children Alcohol Free* – was held January 10-11, 2002, Washington, D.C., and attracted more than 300 participants representing 49 States, Puerto Rico and the District of Columbia. This represented twice as many states and participants than had attended the first national conference in March 2000.

TITLE: Curriculum for Colleges of Pharmacy

AWARD: \$20,000

CONTACT: Deborah R. Maiese

HRSA

NIH/ORWH agrees to transfer \$20,000 to HRSA MCHB to support the work of the American Association of Colleges of Pharmacy, to conduct analytical activities needed to:

better understand the degree to which women's health issues are addressed within the pharmacy curriculum;

develop a curricular framework (content and desired student outcomes) on women's health; and develop educational resources (instructional materials and assessment tools) to facilitate the incorporation of these outcomes and content into the professional degree program in pharmacy, continuing professional development programs for pharmacists, and interdisciplinary health professions education.

A three part strategy will be as follows:

Part I: Survey to assess curricular coverage of women's health in colleges and schools of pharmacy

Part II: Analysis of adequacy of existing evidence-based resources and teaching materials; and

Part III: Modular development of new materials for teaching health professions students and practitioners, including interdisciplinary education and practice activities.

TITLE: Osteoarthritis Initiative

NIAMS

AWARD: \$800,000

CONTACT: Steve Katz, M.D.

Osteoarthritis (OA), the most common form of arthritis, is a painful joint disease marked by the gradual wearing away of cartilage that cushions and protects the bones. More than 20 million people in the U.S. have this disease, which mostly occurs in older people but can affect younger men and women. The knee is among the most commonly affected joints. There are currently no treatments that change the course of the disease, and clinical trials for prospective therapies are long, difficult and expensive.

The Osteoarthritis Initiative (OAI) is a collaboration between the federal National Institutes of Health (NIH) and pharmaceutical companies to pool funds and expertise for a public repository of OA patient data, radiological information and biological specimens. Scientists will be able to use this public resource to test much-needed biochemical and imaging markers of disease progression, to further the development of OA drugs, and to improve public health. Neither the federal nor private sector alone would be able to develop such a resource.

Scientists, health care providers and drug companies need biochemical and imaging markers of how OA progresses in order to diagnose, monitor, and develop and implement treatments for this condition. Current methods of evaluating disease progression, including x rays and blood tests, are not accurate enough to be used in clinical trials of potential treatments. The data and specimen repository will establish standards of disease progression against which potential biochemical and imaging markers can be evaluated and clinical trials of promising agents will be facilitated.

NIH solicited and reviewed applications and awarded research contracts for 4-6 clinical centers and 1 coordinating center to create the repository. Following participant recruitment, data and specimens will be collected over 5 to 7 years from approximately 5,000 people at high risk for OA. In addition to conducting a longitudinal natural history study, scientists will collect blood and carry out imaging studies of the hips, hands and knees throughout the study.

The initiative is coordinated by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Institute on Aging (NIA), with additional support from the National Institute of Dental and Craniofacial Research, the Office of Research on Women's Health, the National Center on Minority Health and Health Disparities, the National Center for Complementary and Alternative Medicine, the National Center for Research Resources, the Office of Technology Transfer, the Office of the General Counsel, and the Office of Science Policy, all parts of NIH. These NIH institutes and offices form the public part of the partnership. The private-sector partners are GlaxoSmithKline, Merck, Novartis, and Pfizer, DHHS's component involved is the Center for Drug Evaluation and Research of the FDA. Funding for the OAI is being managed by the Foundation for the National Institutes of Health, Inc.